Biotechnology Risk Assessment Research Grants Program

2014 Request for Applications

LETTER OF INTENT RECEIPT DATE: January 17, 2014
APPLICATION DEADLINE: March 19, 2014

U.S. Department of Agriculture

National Institute of Food and Agriculture

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE; U.S. DEPARTMENT OF AGRICULTURE

BIOTECHNOLOGY RISK ASSESSMENT RESEARCH GRANTS PROGRAM

INITIAL ANNOUNCEMENT

CATALOG OF FEDERAL DOMESTIC ASSISTANCE: This program is listed in the Catalog of Federal Domestic Assistance under 10.219, Biotechnology Risk Assessment Research.

DATES: Letters of Intent (LOI) are required and must be received by **5:00 p.m. Eastern Time** on **Friday, January 17, 2014.** Applications must be received by **5:00 p.m. Eastern Time** on **Tuesday, March 19, 2014**. Comments regarding this request for applications (RFA) are requested within six months from the issuance of this notice. Comments received after that date will be considered to the extent practicable.

STAKEHOLDER INPUT: The National Institute of Food and Agriculture (NIFA) seeks your comments about this RFA. We will consider the comments when we develop the next RFA for the program, if applicable, and we'll use them to meet the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7613(c)(2)). Submit written stakeholder comments by the deadline set forth in the DATES portion of this Notice to: Policy and Oversight Division; Office of Grants and Financial Management; National Institute of Food and Agriculture; USDA; STOP 2299; 1400 Independence Avenue, SW; Washington, DC 20250-2299; or via e-mail to: Policy@nifa.usda.gov. (This e-mail address is intended only for receiving comments regarding this RFA and not requesting information or forms.) In your comments, please state that you are responding to the Biotechnology Risk Assessment Research Grants Program RFA.

EXECUTIVE SUMMARY: NIFA announces the availability of grant funds and requests applications for the Biotechnology Risk Assessment Research Grants Program (BRAG) for fiscal year (FY) 2014 to support environmental assessment research concerning the introduction of genetically engineered (GE) organisms into the environment. NIFA is currently operating under temporary appropriations as part of the Continuing Resolution (CR) providing funds through January 15, 2014. Based on the current CR, NIFA anticipates the amount available for this program in FY 2014 will be approximately $4 million. Adjustments will be made to program allocations once the FY 2014 appropriations are finalized.

This notice identifies the objectives for BRAG projects, the eligibility criteria for projects and applicants, and the application forms and associated instructions needed to apply for a BRAG grant.

Changes in the FY 2014 RFA. In FY 2014, submission of a full proposal application with a corresponding LOI is required (with exception of conference grant applications). LOI must be received by **5:00 p.m. Eastern Time** on **Friday, January 17, 2014.** For instructions on how to prepare a LOI, please see Part IV, A.

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PART I—FUNDING OPPORTUNITY DESCRIPTION

A. Legislative Authority and Background

Authority for the BRAG program is contained in section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921) and amended in section 7210 of the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 7901) (Pub. L. 107-171). In accordance with the legislative authority in the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 7901), the BRAG program supports research designed to identify and develop appropriate management practices to minimize physical and biological risks associated with genetically engineered animals, plants, and microorganisms. NIFA and the Agricultural Research Service (ARS) of the U.S. Department of Agriculture (USDA) jointly administer the BRAG program. The administrative regulations for this program are found at 7 CFR 3415 and 7 CFR 3430.

B. Purpose and Priorities

The purpose of the BRAG program is to support the generation of new information that will assist Federal regulatory agencies in making science-based decisions about the environmental effects of introducing organisms genetically engineered (GE) by recombinant and/or synthetic nucleic acid techniques. Such organisms can include plants, microorganisms (including fungi, bacteria, and viruses), arthropods, fish, birds, mammals and other animals excluding humans. Investigations of effects on both managed and natural environments are relevant. The BRAG program accomplishes its purpose by providing Federal regulatory agencies with relevant scientific information.

The BRAG program receives input regarding its program priorities through multiple regulatory agencies that have an interest in the environmental risk related to the introduction of GE organisms. In addition, the BRAG program seeks input from USDA's Advisory Committee and the 21st Century Agriculture (AC21) (http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=AC21Main.xml). The BRAG program supports applied and/or fundamental risk assessment research relevant to environmental risk assessment, including biological risk, and the Federal regulatory process. When evaluating GE organisms, Federal regulators must answer the following four general questions:

1. Is there a hazard? (Potential hazard identification);

2. How likely is the hazard to occur? (Quantifying the probability of occurrence; identifying likely exposure scenarios);

3. What is the severity and extent of the hazard if it occurs? (Quantifying the effects); and

4. Is there an effect above and beyond what might occur with an unmodified organism or an organism that has similar traits, but was developed using other technologies?

The BRAG program will also support risk management research, which is defined to include either: (1) research aimed primarily at reducing negative effects of specific biotechnology-

derived agents; or (2) a policy and decision-making process that uses risk assessment data in deciding how to avoid or mitigate the negative consequences identified in a risk assessment. Although Project Director(s) (PDs) are not required to perform actual risk assessments as part of the research they propose, they should design studies that will provide useful science-based information for Federal regulators assessing GE organisms**.**

Applications to the BRAG program must address one of the following program areas or seek partial funding for a conference that addresses risk assessment or risk management of GE organisms released into the environment (See Part I, C. for more detailed descriptions):

1. Research designed to identify and develop appropriate management practices to minimize physical and biological risks to the environment associated with GE animals, plants, and micro-organisms;

2. Research designed to develop methods to monitor the dispersal of GE animals, plants, and micro-organisms;

3. Research on the characteristics, rates, and methods of gene transfer between GE animals, plants, or micro-organisms, and wild or non-GE agricultural organisms;

4. Environmental assessment research designed to compare the impacts of animals, plants, and micro-organisms modified through genetic engineering with environmental impacts on non-GE production systems; or

5. Other areas of research designed to further the purposes of the BRAG program.

Awards will not be made for research in any of the following areas: food safety risk assessment or risk management; health risk assessment or risk management of humans or domestic food animals exposed to GE organisms, including clinical trials; methods for seed storage; commercial product development; product marketing strategies; or other research unrelated to environmental risk assessment or risk management.

C. Program Area Description

Program Area Code – HX

Letters of Intent Receipt - Friday, January 17, 2014 (5:00 p.m., ET)
Application Deadline – Tuesday, March 19, 2014 (5:00 p.m., ET)
Proposed Budget Requests –

Priority Research Proposals **must not exceed $1 million** total (including indirect costs) for project periods up to 4 years.

Standard Research Proposals **must not exceed $500,000** total (including indirect costs) for project periods up to 4 years.

Conference Proposals **must not exceed $25,000** total (no indirect costs are allowed on conference grants).

Requested Project Type – Research Projects

Program Area Contacts:

Dr. Shing Kwok (202-401-6060, skwok@nifa.usda.gov), National Program Leader; Plant Systems-Production; Institute of Food Production and Sustainability; National Institute of Food and Agriculture.

Dr. Mark Mirando (202-401-4336, mmirando@nifa.usda.gov), National Program Leader; Animal Systems; Institute of Food Production and Sustainability; National Institute of Food and Agriculture.

Dr. Jack Okamuro (301-504-5912, mobile: 202-285-9520; jack.okamuro@ars.usda.gov), National Program Leader; Crop Production and Protection; Agricultural Research Service.

NIFA and ARS will competitively award research grants to support biotechnology regulation, thereby helping to address concerns about the effects of introducing genetically engineered (GE) organisms into the environment and helping regulators develop policies regarding such introduction. The BRAG program also encourages proposals seeking partnership with or involvement of international entities where appropriate and domestically beneficial. In addition, the BRAG program is accepting proposals seeking partial funding for a conference that addresses risk assessment or risk management of GE organisms released into the environment.

PRIORITY RESEARCH PROPOSALS

A priority research project must provide viable solutions to the highest priority issues in biotechnology risk assessment research through either applied or fundamental research.

Areas of interest to the BRAG program for a priority grant are:

1. **Comparison between Transformation-associated Genomic Variation and Genomic Variation Introduced by Non-genetic Engineering Approaches in Plants**

   Comparison of the types and frequencies of nucleic acid changes introduced into plant genomes, via genetic insertion techniques versus other plant breeding techniques. Proposed projects must be comparative studies designed to obtain, analyze, and compare data concerning the types and frequencies of unintended phenotypic variation and the types and frequencies of the associated genomic sequence changes by:

   (a) Insertion of DNA with one or more widely used genetic engineering techniques (e.g., particle bombardment, *Agrobacterium*-mediated transformation), **AND**
   (b) One or more other mutation-generating plant breeding techniques (e.g., irradiation or chemical mutagenesis, somatic cell culture and clonal propagation, ploidy alterations, wide interspecies or inter-generic crosses, induced structural changes in chromosomes).

Proposed projects must be conducted in a commercially significant crop species which can include specialty crops and clonally propagated crops. Experimental designs must generate statistically relevant data. These studies should support the assessment of potential unintended effects that may occur from genetic engineering compared to other breeding techniques.

The use of the word "phenotypic variation" above specifically refers to the introduction of unintended changes to the existing phenotype and does NOT include the intended new phenotype introduced. The focus of the project is on the unintended consequences of DNA insertion and not on the consequences of the specific DNA inserted.

2. Development of a Risk Assessment Framework for the Environmental Impacts of GE crops at the Landscape Level

Identification and experimental assessment of potential environmental impacts of large-scale growth of GE crops, with emphasis on plants used for biofuels (e.g., perennial species such as trees or grasses, camelina, sorghum, sugarcane, etc.), to support the development of a risk assessment framework. For the purposes of this priority area, large-scale refers to cultivation on 100 or more acres. Project must address multiple BRAG topic areas, preferentially chosen from (but not limited to) the following:

(a) Strategies for conducting large scale GE field studies with minimal environmental risk;
(b) Landscape level studies to assess environmental impacts of land use changes and/or ecosystem function and services;
(c) Assessment and documentation of significant community or ecosystem effects that are not revealed by studies on small plots: such as effects on plant or animal communities; species displacement; soil health; fertilizer, soil amendment, and pesticide inputs; hydrology; water quality; fire frequency or intensity; toxicant and pesticide residue levels; and/or new plant pests;
(d) Assessment of the likelihood and impact of gene flow to related organisms under various management strategies;
(e) Basic biology and ecology of the species; and/or
(f) Weediness or invasiveness of the GE organism.

Priority Research Proposals must not exceed $1 million (including indirect costs) for project periods up to four years.

STANDARD RESEARCH PROPOSALS

Standard research proposals address issues related to newly developed GE organisms (e.g., trees and other perennials, including biofuel crops are especially sought). Research proposals can be applied and/or fundamental and must address one of the following five program areas:

1. Management Practices to Minimize Environmental Risk of GE Organisms

Research designed to develop appropriate management practices to minimize physical and biological risks to the environment associated with GE animals, plants, and/or microorganisms. Potential areas of research include, but are not limited to:

(a) Evaluation of management, monitoring, and mitigation methodologies for confinement of field trials of GE organisms;
(b) Development of practical management methodologies for reducing the spread and persistence of GE organisms into natural and managed environments;
(c) Development or evaluation of effective bio-confinement strategies, including molecular and/or genetic techniques, to limit gene transfer (gene flow) or outcrossing to sexually compatible organisms;
(d) Mitigation measures to limit gene introgression when GE organisms are released or escaped into the environment, physical containment fails, or biological containment is unavailable;
(e) Development of mechanisms, strategies, and/or tools that foster stewardship and mitigate environmental risks of GE organisms;
(f) Assessment of the impacts of genetic engineering on plant-pest interactions, including impacts on the plants themselves and/or on plant-pest populations; and
(g) Development and/or evaluation of tools for assessing weediness or invasiveness of GE plants relative to unmodified parent organisms.

2. Methods to Monitor Dispersal of GE Organisms

Research designed to develop methods to monitor the dispersal of GE animals, plants, and microorganisms. Potential areas of research include, but are not limited to:

(a) Survivability profile and/or fitness of GE organisms in the wild;
(b) Strategies for large-scale deployment or field studies of GE, with special reference to those considerations that may not be revealed through small-scale evaluation and tests; and/or
(c) Assessing the effects of transgene(s) in engineered animal species that may easily spread, such as birds, aquatic species, arthropods and other invertebrates. This area may include:
    - Studies of transgene stability over multiple generations,
    - Comparative mating competence or reproductive studies,
    - Juvenile and adult viability studies, and/or
    - Comparative behavior and biological studies, including studies addressing whether transgenes can alter host range or ecological interactions.

3. Gene Transfer to Domesticated and Wild Relatives

Research designed to further existing knowledge with respect to the characteristics, rates, and methods of gene transfer (gene flow) that may occur between GE animals, plants, and microorganisms, and related wild and agricultural organisms. Gene flow research should be directed to organisms with a high potential for outcrossing to sexually compatible species and to genes that have a high potential for altering the fitness of the recipient organism for its environment. With regards to plants, preference will be given to studies with species that have

sexually compatible wild relatives in the United States. Potential areas of research include, but are not limited to:

(a) Impacts of gene flow from GE plants, insects, animals, or micro-organisms to related organisms, communities, or ecosystems;
(b) Fate and stability (persistence) of transgenes that have been introgressed by outcrossing into populations of non-transgenic organisms, and the degree to which they confer a selective advantage or disadvantage upon the carriers, especially with regard to transgenes that confer enhanced growth or abiotic stress tolerance;
(c) Measuring impact of transgene placement (nuclear or cytoplasmic) on the transfer and introgression of transgenes into wild and feral plants, animals, or fungi;
(d) Assessing the influence of genetic background on the expression of and phenotypes conferred by regulatory genes, to inform understanding of the characteristics and potential outcomes of gene transfer; and
(e) Data acquisition and modeling of GE organisms or transgene escape into the environment, including modeling to identify parameters that influence gene dispersal and its consequences, with a particular interest in insect-mediated gene movement between plants.

4. Environmental Impacts of GE relative to Non-GE Organisms in the Context of Production Systems

Environmental assessment research which compares the relative impacts of animals, plants, and micro-organisms modified through genetic engineering to other types of production systems. Potential areas of research include, but are not limited to:

(a) The influence of GE crops on ecosystem function;
(b) Assessment of GE *as compared to* non-GE organisms on the impacts of agricultural or forest management systems (e.g., on community structures of agro- or forest ecosystems). Important focus areas are:
    - The presence and function of various types of beneficial organisms,
    - Defining the magnitude of changes in indicator species or communities that could trigger concerns regarding ecosystem impacts,
    - How the biology and ecology of indicator taxa are influenced by geography, seasonal fluctuations, species, etc.); and/or
(c) Assessment of how the introduction of GE organisms alters the impact of agriculture on the rural environment, such as altered land use practices or other aspects of human ecology, species displacement, soil erosion, effects on water quality, or other geographically dispersed events. Comparative management techniques and resources for maintenance of non-GE animals versus GE animals (e.g., changes in land use or manure management practices required for GE animals engineered to utilize feed more efficiently); and
(d) Comparative assessment of environmental impacts of agricultural production systems using organic and/or conventional methods with those involving plant, animal, or microbial biotechnology. Appropriate parameters or metrics are to include, but are not limited to:

- Non target impacts on community structure,
- Soil health, fertilizer, pesticide, and soil amendment inputs,
- Changes in toxicant and pesticide residue levels,
- Prevalence and distribution of weeds, including those with single or multiple herbicide resistance,
- Prevalence, distribution, and damage from pests and pathogens, including emergence of resistance, and/or
- Land use related to yield and productivity.

5. Other Research Topics

Other areas of research designed to further the purposes of the BRAG Program. Potential areas of research include, but are not limited to:

(a) Research focused on the environmental effects of introducing RNA interference transgenes or other gene silencing mechanisms using RNAi, siRNA, or miRNA in animals, plants, microbes and/or insects. Important areas include, but not limited to:
- Assessment of environmental fate and/or persistence of these small RNA molecules; and/or
- Potential off-target, non-target, or unintended effects of these small RNA molecules.

(b) Comparative assessment of GE plants with single vs. multiple transgenes that confer resistance to pests or disease, with the goal of understanding how pests or diseases overcome the conferred resistance. Research focus areas may include:
- The impact of multiple transgenic resistance genes on target pest populations; and/or
- The effects of multiple transgenic resistance genes on non-target species.

Proposals on pest resistance management are not excluded from the program, but any such proposals submitted should describe a clear and significant connection with biotechnology risk assessment/management.

(c) Biological and ecological studies associated with GE perennial species. Studies may focus on:
- Gene flow,
- Environmental risk persistence,
- Dormancy, and other fitness characteristics,
- Ecosystem interactions and potential ecosystem changes when grown in new settings, and/or
- Ecological effects of technologies for reducing the undesired spread of GE organisms.

(d) Development of environmental risk assessment methodologies for GE organisms when there is little baseline data on the unmodified parent organism (e.g., *Panicum virgatum*, *Miscanthus*, *Populus* spp., *Eucalyptus* spp., eukaryotic algae).

Standard Research Proposals must not exceed $500,000 total (including indirect costs) for project periods up to four years.

CONFERENCE PROPOSALS

Applicants to the BRAG program may request partial funding to organize a conference or workshop that brings together scientists, regulators, and other stakeholders to review science-based data relevant to risk assessment or risk management of GE organisms released into the environment. To be eligible for funding, the steering committee for the proposed conference should include representatives from a variety of relevant scientific disciplines, such as ecology, population biology, pathology, production and resource management science, as well as educators, extension specialists and others, as appropriate.

BRAG conference applications should: 1) describe the relevance of the proposed conference to biotechnology risk assessment to U.S. agriculture, 2) explain the uniqueness and timeliness of the conference, 3) outline the qualifications of the organizing committee and the appropriateness of the invited speakers to the topic areas to be covered, 4) state clearly the goals of the conference and the likely outcomes, 5) explain the need for the various elements of the budget, and 6) describe the means by which the organizers will make up the total costs of the conference from other sources.

The goals for the conference should include sharing of scientific information and identification of gaps in knowledge, and/or public education and outreach, among others. Publication of the proceedings is highly encouraged.

Conference Proposals must not exceed $25,000 total. No indirect costs are allowed on conference grants.

PART II—AWARD INFORMATION

A. Available Funding

The National Institute of Food and Agriculture is currently operating under temporary appropriations as part of the Continuing Resolution (CR) providing funds through January 15, 2014. Based on the current CR, NIFA anticipates the amount available for this program in FY 2014 will be approximately $4 million. Adjustments will be made to program allocations once the FY 2014 appropriations are finalized.

There is no commitment by USDA to fund any particular application or to make a specific number of awards.

Awards issued as a result of this RFA will have designated the Automated Standard Applications for Payment System (ASAP), operated by the Department of Treasury's Financial Management Service, as the payment system for funds. For more information see http://www.nifa.usda.gov/business/method_of_payment.html.

B. Types of Applications

In FY 2014, applications may be submitted to the BRAG Program as one of the following four types of requests:

(1) New application. This is a project application that has not been previously submitted to the BRAG Program. We will review all new applications competitively using the selection process and evaluation criteria described in Part V—Application Review Requirements.

(2) Renewal application. Applications for renewed funding must contain the same information as required for new applications; they also must contain a Progress Report (see Project Narrative, Part IV). Renewal applications must be received by the relevant due dates, will be evaluated in competition with other pending applications in the area to which they are assigned, and will be reviewed according to the same evaluation criteria as new applications.

(3) Resubmitted application. This is an application that had previously been submitted to the BRAG Program but not funded. Project Directors (PDs) must respond to the previous review panel summary (see Response to Previous Review, Part IV). Resubmitted applications must be received by the relevant due dates, will be evaluated in competition with other pending applications in appropriate area to which they are assigned, and will be reviewed according to the same evaluation criteria as new applications.

(4) Resubmitted renewal application. This is a project application that requests additional funding for a project beyond the period that was approved in the original award. In addition, this is an application that had previously been submitted for renewal to the BRAG Program but not funded. Therefore, PDs must provide a Progress Report as required under the Project Narrative, Part IV, and must respond to the previous review panel summary as required under Response to Previous Review, Part IV. Resubmitted renewal applications must be received by the relevant

due dates, will be evaluated in competition with other pending applications in the areas to which they are assigned, and will be reviewed according to the same evaluation criteria as new applications.

C. Project Types

Priority research proposals submitted to the BRAG program s**hould not exceed $1 million (including indirect costs)** for project periods up to 4 years of support**.** Standard research proposals **should not exceed $500,000 (including indirect costs)** for project periods up to 4 years of support. Conference proposals **should not exceed $25,000. No indirect costs are allowed on conference grants.** Proposal requests exceeding these limits will be excluded from review.

Project periods for Research grants cannot exceed the statutory time limit of five years.

The BRAG program will not support applications for postdoctoral fellowships.

D. Responsible and Ethical Conduct of Research

The responsible and ethical conduct of research (RCR) is critical for excellence, as well as public trust, in science and engineering. Consequently, we consider education in RCR essential to the preparation of future scientists. In accordance with sections 2, 3, and 8 of 7 CFR Part 3022, institutions that conduct USDA-funded extramural research must foster an atmosphere conducive to research integrity, bear primary responsibility for prevention and detection of research misconduct, and maintain and effectively communicate and train their staff regarding policies and procedures. In the event an application to NIFA results in an award, the Authorized Organizational Representative (AOR) assures, through acceptance of the award that the institution will comply with the above requirements. Per award terms and conditions, grant recipients shall, upon request, make available to NIFA the policies, procedures, and to support the conduct of the training.

Note that the training referred to herein shall be either on-campus or off-campus training. The general content of the ethics training will, at a minimum, emphasize three key areas of research ethics: authorship and plagiarism, data and research integration, and reporting misconduct. Each institution will be responsible for developing its own training system, as schools will need flexibility to develop training tailored to their specific student needs. Grantees should consider the Collaborative Institutional Training Initiative (CITI) program for RCR (https://www.citiprogram.org/rcrpage.asp). Typically this RCR education addresses the topics of: Data Acquisition and Management - collection, accuracy, security, access; Authorship and Publication; Peer Review; Mentor/Trainee Responsibilities; Collaboration; Conflict of Interest; Research Misconduct; Human Subject Research; and Use of Animals in Research.

PART III—ELIGIBILITY INFORMATION

A. Eligible Applicants

Applications may be submitted by any United States public or private research or educational institution or organization. Award recipients may subcontract to organizations not eligible to apply provided such organizations are necessary for the conduct of the project. Failure to meet an eligibility criterion by the time of application deadline may result in the application being excluded from consideration or, even though an application may be reviewed, will preclude NIFA from making an award.

B. Cost Sharing or Matching

NIFA does not require matching support for this program. Applications will be peer reviewed and selected for funding without regard to matching resources.

PART IV—APPLICATION AND SUBMISSION INFORMATION

A. Letter of Intent (LOI) Instructions

In FY 2014, in order to submit a full proposal, you must submit a LOI (with the exception of conference grant applications).

Please follow the guidelines below for LOI submission requirements

1. The Letter of Intent must adhere to the following formatting guidelines:
   a. Font size must be at least 12 point
   b. Margins must be at least one inch in all directions
   c. Line spacing must not exceed six lines of text per vertical inch

2. The Letter of Intent is limited to **two pages** for all project and grant types.
   a. On Page 1, provide **only** the following information:
      i. the name, professional title, department, institution, and *e*-mail address of the lead project director (PD) and name, professional title, department, and institution of all collaborating investigators
      ii. the Program Area or the Priority Area that is most closely addressed in the application
   b. On Page 2, include:
      i. a descriptive title
      ii. rationale
      iii. overall hypothesis or goal
      iv. specific objectives
      v. approach
      vi. potential impact and expected outcomes

3. When submitting LOI, NIFA will only accept LOI in the portable document format (PDF). Attach the PDF LOI to an e-mail addressed to Dr. Shing Kwok (skwok@nifa.usda.gov). In the e-mail subject line, write: Letter of Intent [Program Area Code] _ [PDs Last Name].

4. **A Letter of Intent is required for all grant types, except Conference Grant applications.**

5. Submission of more than one Letter of Intent to a program is discouraged.

6. An acknowledgement receipt will be sent via email by replying to the sender within five business days.

7. Letters of Intent will be reviewed by scientific program staff in order to plan for appropriate expertise for the peer review panel and ensure that the proposed project fits appropriately within the Program Area Priorities.

8. You must notify the appropriate Program Area Contact of any changes to key project personnel, title, or objectives between the submission of the LOI and the full application.

9. **The Letter of Intent due date is January 17, 2014 at 5:00 pm ET.**

B. Electronic Application Package

Only electronic applications may be submitted via Grants.gov to NIFA in response to this RFA. We urge to submit early to the Grants.gov system. For an overview of the Grants.gov application process see http://www.grants.gov/web/grants/applicants/grant-application-process.html.

New Users of Grants.gov

Prior to preparing an application, we recommend that the PD/PI first contact an Authorized Representative (AR, also referred to as Authorized Organizational Representative or AOR) to determine if the organization is prepared to submit electronic applications through Grant.gov. If not (e.g., the institution/organization is new to the electronic grant application process through Grants.gov), then the one-time registration process must be completed **PRIOR** to submitting an application. It can take as long as 2 weeks to complete the registration process so it is critical to begin as soon as possible. In such situations, the AR should go to **"Register" in the top right corner of the Grants.gov web page (or go to** http://www.grants.gov/web/grants/register.html**) for information on registering the institution/organization with Grants.gov.** Item 2. below mentions the "NIFA Grants.gov Application Guide." Part II.1. of the NIFA Grants.gov Application Guide contains additional explanatory language regarding the registration process.

Steps to Obtain Application Package Materials

To receive application materials:

1. You must download and install a version of Adobe Reader compatible with Grants.gov to access, complete, and submit applications. For basic system requirements and download instructions, seehttp://www.grants.gov/web/grants/support/technical-support/software/adobe-reader-compatibility.html. Grants.gov has a test package that will help you determination whether your current version of Adobe Reader is compatible.

2. To obtain the application package from Grants.gov, go to http://www.grants.gov, click on "Applicants" in the navigation bar at the top of the page and then click on the "Apply for Grant Opportunities" link under the "Apply for Grant" heading. Under Step 1 click on "Download a Grant Application Package," and enter the funding opportunity number **USDA-NIFA-BRAP-004388** in the appropriate box and click "Download Package." From the search results, click "Download" to access the application package.

   Contained within the application package is the "NIFA Grants.gov Application Guide." This guide contains an introduction and general Grants.gov instructions, information about how to use a Grant Application Package in Grants.gov, and instructions on how to complete the application forms.

   If you require assistance to access the application package (e.g., downloading or navigating Adobe forms) **or submitting the application,** refer to resources available on the Grants.gov website (http://www.grants.gov/web/grants/applicants/applicant-resources.html). Grants.gov assistance is also available at:

Grants.gov customer support
800-518-4726 Toll-Free or 606-545-5035
Business Hours: 24 hours a day, 7 days a week. Closed on federal holidays.
Email: support@grants.gov

Grants.gov iPortal: Top 10 requested help topics (FAQs), Searchable knowledge base, self-service ticketing and ticket status, and live web chat (available 7 am - 9 p.m. ET). Get help now!

Have the following information available when contacting Grants.gov:

- Funding Opportunity Number (FON)
- Name of agency you are applying to
- Specific area of concern

See http://www.nifa.usda.gov/funding/electronic.html for additional resources for applying electronically.

C. Content and Form of Application Submission

You should prepare electronic applications following Parts V and VI of the NIFA Grants.gov Application Guide. This guide is part of the corresponding application package (see Section A. of this Part). The following is **additional information** needed to prepare an application in response to this RFA. **If there is discrepancy between the two documents, the information contained in this RFA is overriding.**

Note the attachment requirements (e.g., PDF) in Part III section 3. of the guide. ANY PROPOSALS THAT ARE NON-COMPLIANT WITH THE REQUIREMENTS (e.g., content format, PDF file format, file name restrictions, and no password protected files) WILL BE AT RISK OF BEING EXCLUDED FROM NIFA REVIEW. Partial applications will be excluded from NIFA review. We will accept subsequent submissions of an application until close of business on the closing date in the RFA (see Part V, 2.1 of the NIFA Grants.gov Application Guide for further information).

Grants.gov provides online tools to assist if you do not own PDF-generating software. You will find PDF conversion software at http://test.grants.gov/web/grants/support/technical-support/software/pdf-conversion-software.html.

For any questions related to the preparation of an application, review the NIFA Grants.gov Application Guide and the applicable RFA. If assistance is still needed for preparing application forms content, contact:

- Email: electronic@nifa.usda.gov
- Phone: 202-401-5048
- Business hours: Monday through Friday, 7 a.m. – 5 p.m. ET, excluding federal holidays.

1. SF 424 R&R Cover Sheet
Information related to the questions on this form is dealt with in detail in Part V, 2. of the NIFA Grants.gov Application Guide.

2. SF 424 R&R Project/Performance Site Location(s)
Information related to the questions on this form is dealt with in detail in Part V, 3. of the NIFA Grants.gov Application Guide.

3. R&R Other Project Information Form
Information related to the questions on this form is dealt with in detail in Part V, 4. of the NIFA Grants.gov Application Guide.

a. Field 7. Project Summary/Abstract. The summary should also include the relevance of the project to the goals of the BRAG program. Please find the suggested Project Summary/Abstract Template at: http://www.nifa.usda.gov/home/faq_apply.html#abstract.

b. Field 8. Project Narrative.

PLEASE NOTE: The Project Narrative shall not exceed 18 pages of written text including figures and tables regardless of whether it is single or double spaced. Use an easily readable font face (e.g., Geneva, Helvetica, Times New Roman). This maximum page limit has been established to ensure fair and equitable competition. The Project Narrative must include all of the following:

(1) Introduction. A clear statement of the long-term goals and supporting objectives of the proposed project should preface the project description. The most significant published work in the field under consideration, including the work of key project personnel on the current application, should be reviewed. The current status of research in the particular scientific field also should be described.

(2) Progress report. Renewal applications and resubmitted renewal applications (as described in Part II, B.) should include a clearly marked performance report describing results to date from the previous award. This section should contain the following information: (1) a comparison of actual accomplishments with the goals established for the previous award; (2) the reasons established goals were not met, if applicable; and (3) a listing of any publications resulting from the previous award. Copies of reprints or preprints may be included in the Appendices to Project Narrative portion of the submission.

(3) Rationale and significance. Present concisely the rationale for the proposed project. The project's specific relationship and relevance to the program area in which an application is submitted (see Part I, C.) and its specific relationship and relevance to potential regulatory issues of United States biotechnology research should be shown clearly. Any novel ideas or contributions that the proposed project offers should also be discussed in this section.

(4) Experimental plan. The hypotheses or questions being asked and the methodology to be applied to the proposed project should be stated explicitly. Specifically, this section must

include: (1) a description of the investigations and/or experiments proposed and the sequence in which the investigations or experiments are to be performed; (2) techniques to be used in carrying out the proposed project, including the feasibility of the techniques; (3) results expected; (4) means by which experimental data will be analyzed or interpreted; (5) pitfalls that may be encountered; (6) limitations to proposed procedures; and (7) a tentative schedule for conducting major steps involved in these investigations and/or experiments.

In the experimental plan, you must explain fully any materials, procedures, situations, or activities that may be hazardous to personnel (whether or not they are directly related to a particular phase of the proposed project), along with an outline of precautions to be exercised to avoid or mitigate the effects of such hazards.

a. Field 9. Bibliography & References Cited. All work cited, including that of key personnel, should be referenced in this section of the application.

b. Field 12. Other Attachments:

1. Response to Previous Review. This requirement only applies to "Resubmitted Applications" and "Resubmitted Renewal Applications" as described in Part II, B. PDs must respond to the previous review panel summary on no more than one (1) page, titled "RESPONSE TO PREVIOUS REVIEW."

2. Cooperation and Institutional Units Involved. Cooperative, multi-institutional and multidisciplinary applications are encouraged. Where applicable, identify each institutional unit contributing to the project and designate the lead institution or institutional unit. Clearly define the programmatic roles, responsibilities and budget for each institutional partner.

3. Appendices to Project Narrative. Appendices to the Project Narrative are allowed if they are directly germane to the proposed project. The addition of appendices should not be used to circumvent the text and/or figures and tables page limitations.

4. Collaborative Arrangements. If it will be necessary to enter into formal consulting or collaborative arrangements with others, such arrangements should be fully explained and justified. If the consultants or collaborators are known at the time of application, a vitae or resume and Statement of Work (SOW) should be provided. In addition, evidence (e.g., letter of support) should be provided that the collaborators involved have agreed to render these services. Also, you are required to provide additional information on consultants and collaborators in the budget portion of the application.

4. R&R Senior/Key Person Profile (Expanded)

Information related to the questions on this form is dealt with in detail in Part V, 5. of the NIFA Grants.gov Application Guide. The number of Co-PDs is limited to eight (8). Please do not list more than this number.

Also, **you must attach** 'Current and Pending Support' information for each senior/key person identified above. Please find suggested Current and Pending Support Template at: http://www.nifa.usda.gov/home/faq_apply.html#current. **Note: Even if no other funding is**

currently reported under the 'Active' section of this attachment, you must still list information for this grant application under the 'Pending' section of this attachment for each senior/key person identified above. Also note: The salary amounts requested for Senior/Key personnel should be below or commensurate with the stated time commitment listed on the Current and Pending Form. A person cannot draw a salary amount for time on the project which exceeds the time committed on the Current and Pending Form.

5. R&R Personal Data – As noted in Part V, 6. of the NIFA Grants.gov Application Guide, the submission of this information is voluntary and is not a precondition of award. If completing the information, **do not enter any data in the field requesting the social security number.**

6. R&R Budget

Information related to the questions on this form is dealt with in detail in Part V, 7 of the NIFA Grants.gov Application Guide.

Beginning the first year of funding, excluding a conference award, the PD of a funded project will be required to attend annual investigator meetings either in the metropolitan Washington, DC area or another location (to be determined at a later date) for the duration of the award. Reasonable travel expenses should be included as part of the project budget.

Matching: NIFA does not require matching support for this program and matching resources will not be factored into the review process as evaluation criteria.

7. Supplemental Information Form

Information related to the questions on this form is dealt with in detail in Part VI, 1. of the NIFA Grants.gov Application Guide.

a. Field 2. Program Code. Enter the program code name "**Biotechnology Risk Assessment**" and the program code "**HX**".

b. Field 8. Conflict of Interest List. Conflict of interest information is required for each senior/key person included in the R&R Senior/Key Person Profile. See Part VI, 1.8 of the NIFA Grants.gov Application Guide for further instructions and a link to a suggested template.

D. Submission Dates and Times

Instructions for submitting an application are included in Part IV, Section 1.9 of the NIFA Grants.gov Application Guide.

Applications must be received by Grants.gov by COB on **Tuesday, March 19, 2014** (5:00 p.m. Eastern Time). Applications received after this deadline will normally not be considered for funding. The agency strongly encourages you to submit applications well before the deadline to allow time for correction of technical errors identified by Grants.gov.

If you have problems with the submission of an application to Grants.gov, you are encouraged to FIRST contact the Grants.gov Help Desk to resolve any problems. Keep a record of any such correspondence. See Part IV. A. for Grants.gov contact information.

We send email correspondence to the AR regarding the status of submitted applications (see Part IV. C.). Therefore, applicants are strongly encouraged to provide accurate e-mail addresses, where designated, on the SF-424 R&R Application for Federal Assistance.

If the AR has not received correspondence **from NIFA** regarding a submitted application within 30 days of the established deadline, please contact the Program Contact identified in Part VII of the applicable RFA and request the proposal number assigned to the application. **Failure to do so may result in the application not being considered for funding by the peer review panel. Once the application has been assigned a proposal number, this number should be cited on all future correspondence.**

E. Funding Restrictions

The use of grant funds to plan, acquire, or construct a building or facility is not allowed under this program. With prior approval, and in accordance with the cost principles set forth in the Office of Management and Budget (OMB) Circular No. A-21, (codified at 2 CFR 220), some grant funds may be used for minor alterations, renovations, or repairs deemed necessary to retrofit existing teaching or research spaces in order to carry out a funded project. However, requests to use grant funds for such purposes must demonstrate that the alterations, renovations, or repairs are essential to achieving the major purpose of the project. Grant funds may not be used for endowment investing.

Section 720 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Programs (HR 112-284), limited indirect costs to 30 percent of the total Federal funds provided under each award. Therefore, when preparing budgets, you should limit your requests for recovery of indirect costs to the lesser of their institution's official negotiated indirect cost rate or the equivalent of 30 percent of total Federal funds awarded.

F. Other Submission Requirements

You should follow the submission requirements noted in Part IV, section 1.9 in the document entitled "NIFA Grants.gov Application Guide."

For information about the **status of a submitted application**, see Part III., section 6. of the NIFA Grants.gov Application Guide.

PART V—APPLICATION REVIEW REQUIREMENTS

A. General

We evaluate each application in a 2-part process. First, we screen each application to ensure that it meets the administrative requirements as set forth in this RFA. Second, a review panel will technically evaluate applications that meet these requirements.

We select reviewers based upon their training and experience in relevant scientific, extension, or education fields, taking into account the following factors: (a) The level of relevant formal scientific, technical education, or extension experience of the individual, as well as the extent to which an individual is engaged in relevant research, education, or extension activities; (b) the need to include as reviewers experts from various areas of specialization within relevant scientific, education, or extension fields; (c) the need to include as reviewers other experts (e.g., producers, range or forest managers/operators, and consumers) who can assess relevance of the applications to targeted audiences and to program needs; (d) the need to include as reviewers experts from a variety of organizational types (e.g., colleges, universities, industry, state and federal agencies, and private profit and non-profit organizations) and geographic locations; (e) the need to maintain a balanced composition of reviewers with regard to minority and female representation and an equitable age distribution; and (f) the need to include reviewers who can judge the effective usefulness to producers and the general public of each application.

B. Evaluation Criteria

The evaluation criteria below will be used in reviewing applications submitted in response to this RFA:

The evaluation criteria identified in 7 CFR 3415.15 (see below) will be used to review all applications submitted in response to this RFA except applications that seek funding for conferences.

Criteria for Evaluating Priority and Standard Research Applications:

1. Scientific merit of the proposal.
    - Conceptual adequacy of hypothesis;
    - Clarity and delineation of objectives;
    - Adequacy of the description of the undertaking and suitability and feasibility of methodology;
    - Demonstration of feasibility through preliminary data;
    - Probability of success of project;
    - Novelty, uniqueness and originality; and
    - Appropriateness to regulation of biotechnology and risk assessment.

2. Qualifications of proposed project personnel and adequacy of facilities.

- Training and demonstrated awareness of previous and alternative approaches to the problem identified in the proposal, and performance record and/or potential for future accomplishments;
- Time allocated for systematic attainment of objectives;
- Institutional experience and competence in subject area; and
- Adequacy of available or obtainable support personnel, facilities, and instrumentation.

3. Relevance of project to solving biotechnology regulatory uncertainty for United States agriculture.

- Scientific contribution of research in leading to important discoveries or significant breakthroughs in announced program areas; and
- Relevance of the risk assessment research to agriculture and environmental regulations.

Criteria for Evaluating Scientific Research Conference Applications:

1. Relevance and timeliness of topics and selection of appropriate speakers;

2. General format of the conference, especially with regard to its appropriateness for fostering scientific exchange and/or public understanding;

3. Provisions for wide participation from the scientific and regulatory community and others, as appropriate;

4. Qualifications of the organizing committee;

5. Appropriateness of the budget requested; and

6. Qualifications of project personnel.

C. Conflicts of Interest and Confidentiality

During the peer evaluation process, we take extreme care to prevent any actual or perceived conflicts of interest that may impact review or evaluation. For the purpose of determining conflicts of interest, we determine the academic and administrative autonomy of an institution by reference to the current Higher Education Directory, published by Higher Education Publications, Inc., 1801 Robert Fulton Drive, Suite 340, Reston, VA, 20191. Phone: (888) 349-7715. Web site: http://www.hepinc.com.

Names of submitting institutions and individuals, as well as application content and peer evaluations, are kept confidential, except to those involved in the review process, to the extent permitted by law. In addition, the identities of peer reviewers will remain confidential throughout the entire review process, to the extent permitted by law, therefore, the names of the reviewers will not be released to applicants.

D. Organizational Management Information

Specific management information relating to an applicant shall be submitted on a one time basis, with updates on an as needed basis. This requirement is part of the responsibility determination prior to the award of a grant identified under this RFA, if such information has not been provided previously under this or another NIFA program. We will provide you copies of forms recommended for use in fulfilling these requirements as part of the preaward process. Although an applicant may be eligible based on its status as one of these entities, there are factors that may exclude an applicant from receiving federal financial and nonfinancial assistance and benefits under this program (e.g., debarment or suspension of an individual involved or a determination that an applicant is not responsible based on submitted organizational management information).

PART VI—AWARD ADMINISTRATION

A. General

Within the limit of funds available for such purpose, the NIFA awarding official shall make grants to those responsible, eligible applicants whose applications are judged most meritorious under the procedures set forth in this RFA. The date specified by the NIFA awarding official as the effective date of the grant shall be no later than September 30 of the federal fiscal year in which the project is approved for support and funds are appropriated for such purpose, unless otherwise permitted by law. The project need not be initiated on the grant effective date, but as soon thereafter as practical so that project goals may be attained within the funded project period. All funds granted by NIFA under this RFA may be used only for the purpose for which they are granted in accordance with the approved application and budget, regulations, terms and conditions of the award, applicable federal cost principles, USDA assistance regulations (parts 3015 and 3019 of 7 CFR), and NIFA General Awards Administration Provisions at 7 CFR part 3430, subparts A through E.

B. Award Notice

The award document will provide pertinent instructions and information including, at a minimum:

(1) Legal name and address of performing organization or institution to whom the director has issued an award under the terms of this request for applications;

(2) Title of project;

(3) Name(s) and institution(s) of PDs chosen to direct and control approved activities;

(4) Identifying award number assigned by NIFA;

(5) Project period, specifying the amount of time NIFA intends to support the project without requiring recompetition for funds;

(6) Total amount of financial assistance approved for the award;

(7) Legal authority(ies) under which the award is issued;

(8) Appropriate Catalog of Federal Domestic Assistance (CFDA) number;

(9) Applicable award terms and conditions (see http://www.nifa.usda.gov/business/awards/awardterms.html to view NIFA award terms and conditions);

(10) Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the award; and

(11) Other information or provisions deemed necessary by NIFA to carry out its respective awarding activities or to accomplish the purpose of a particular award.

C. Administrative and National Policy Requirements

Several federal statutes and regulations apply to grant applications considered for review and to project grants awarded under this program. These include, but are not limited to:

2 CFR Part 220—Cost Principles for Educational Institutions (OMB Circular A-21).

2 CFR Part 225—Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A-87).

2 CFR Part 230—Cost Principles for Non-profit Organizations (OMB Circular A-122).

7 CFR Part 1, subpart A—USDA implementation of the Freedom of Information Act.

7 CFR Part 3—USDA implementation of OMB Circular No. A-129 regarding debt collection.

7 CFR Part 15, subpart A—USDA implementation of Title VI of the Civil Rights Act of 1964, as amended.

7 CFR Part 331 and 9 CFR Part 121—USDA implementation of the Agricultural Bioterrorism Protection Act of 2002.

7 CFR Part 3015—USDA Uniform Federal Assistance Regulations, implementing OMB directives (i.e., OMB Circular Nos. A-21, A-87, and A-122, now codified at 2 CFR Parts 220, 225 and 230), and incorporating provisions of 31 U.S.C. 6301-6308 (formerly the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. No. 95-224), as well as general policy requirements applicable to recipients of departmental financial assistance.

7 CFR Part 3016—USDA Implementation of Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

7 CFR Part 3017—USDA implementation of Governmentwide Debarment and Suspension (Nonprocurement).

7 CFR Part 3018—USDA implementation of Restrictions on Lobbying. Imposes prohibitions and requirements for disclosure and certification related to lobbying on recipients of federal contracts, grants, cooperative agreements, and loans.

7 CFR Part 3019—USDA implementation of OMB Circular A-110, Uniform Administrative Requirements for Grants and Other Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations (2 CFR Part 215).

7 CFR Part 3021—USDA Implementation of Governmentwide Requirements for Drug-Free Workplace (Grants).

7 CFR Part 3022—Research Institutions Conducting USDA-Funded Extramural Research; Research Misconduct.

7 CFR Part 3052—USDA implementation of OMB Circular No. A-133, Audits of States, Local Governments, and Nonprofit Organizations.

7 CFR Part 3407—USDA procedures to implement the National Environmental Policy Act of 1969, as amended.

7 CFR 3430—Competitive and Noncompetitive Non-formula Financial Assistance Programs--General Award Administrative Provisions.

29 U.S.C. 794 (section 504, Rehabilitation Act of 1973) and 7 CFR Part 15b (USDA implementation of statute) —prohibiting discrimination based upon physical or mental handicap in federally-assisted programs.

35 U.S.C. 200 et seq. —Bayh Dole Act, controlling allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in federally-assisted programs (implementing regulations are contained in 37 CFR Part 401).

D. Expected Program Outputs and Reporting Requirements

1. Expected Program Outputs

Project Directors are expected to participate in a one- to two-day PD meeting (excluding conference proposal awardees) in the metropolitan Washington, DC area or another location (to be determined at a later date). An oral briefing for representatives of a regulatory agency may be scheduled during this time. Reasonable travel expenses may be claimed as part of the project budget.

2. Reporting Requirements

Grantees are to submit initial project information and annual and summary reports to NIFA's electronic, Web-based inventory system that facilitates both grantee submissions of project outcomes and public access to information on Federally-funded projects. The details of these reporting requirements are included in the award terms and conditions. Details of annual and final technical reporting requirements also are included in the award terms and conditions.

Any additional reporting requirements will be identified in the terms and conditions of the award (see Part VI, B.9. for a link to view the NIFA award terms and conditions).

PART VII—AGENCY CONTACTS

You and other interested parties are encouraged to contact:

Programmatic Contact -

Dr. Shing F. Kwok; National Program Leader; Institute of Food Production and Sustainability; National Institute of Food and Agriculture; U.S. Department of Agriculture; 800 9th St., SW; Washington, DC 20024; telephone: (202) 401-6060; fax: (202) 401-6071; e-mail: skwok@nifa.usda.gov.

Dr. Mark Mirando; National Program Leader; Institute of Food Production and Sustainability; National Institute of Food and Agriculture; U.S. Department of Agriculture; 800 9th St., SW; Washington, DC 20024; telephone: (202) 401-4336; fax: (202) 401-6071; e-mail: mmirando@nifa.usda.gov.

Dr. Jack Okamuro; National Program Leader; Agricultural Research Service; U.S. Department of Agriculture; George Washington Carver Center, Room 4-2220; 5601 Sunnyside Avenue; Beltsville, MD 20705-5139; telephone: (301) 504-5912; mobile: (202) 285-9520; e-mail: jack.okamuro@ars.usda.gov.

Administrative/Business Contact –

Duane Alphs; Team Leader, Team II, Section II; Office of Grants and Financial Management; National Institute of Food and Agriculture; 1400 Independence Avenue SW, Stop 2201 Washington, DC 20250-2201; telephone (202) 401-4326; fax: (202) 401-6271; email dalphs@nifa.usda.gov.

Rochelle McCrea; Team Leader, Team I; Office of Grants and Financial Management; National Institute of Food and Agriculture; 1400 Independence Ave., SW; STOP 2271 Washington, DC 20250-2271; telephone (202) 401-2880; fax: (202) 401-6271; email: rmccrea@nifa.usda.gov.

PART VIII—OTHER INFORMATION

A. Access to Review Information

We will send copies of reviews, not including the identity of reviewers, and a summary of the panel comments to the applicant PD after the review process has been completed.

B. Use of Funds; Changes

1. Delegation of Fiscal Responsibility

Unless the terms and conditions of the award state otherwise, awardees may not in whole or in part delegate or transfer to another person, institution, or organization the responsibility for use or expenditure of award funds.

2. Changes in Project Plans

a. The permissible changes by the awardee, PD(s), or other key project personnel in the approved project shall be limited to changes in methodology, techniques, or other similar aspects of the project to expedite achievement of the project's approved goals. If the awardee or the PD(s) is uncertain as to whether a change complies with this provision, the question must be referred to the Authorized Departmental Officer (ADO) for a final determination. The ADO is the signatory of the award document, not the program contact.

b. The awardee must request, and the ADO must approve in writing, all changes in approved goals or objectives prior to effecting such changes. In no event shall requests be approved for changes that are outside the scope of the original approved project.

c. The awardee must request, and the ADO must approve in writing, all changes in approved project leadership or the replacement or reassignment of other key project personnel, prior to effecting such changes.

d. The awardee must request, and the ADO must approve in writing, all transfers of actual performance of the substantive programmatic work in whole or in part and provisions for payment of funds, whether or not federal funds are involved, prior to effecting such transfers, unless prescribed otherwise in the terms and conditions of the award.

e. The project period may be extended without additional financial support, for such additional period(s) necessary to complete or fulfill the purposes of an approved project, but in no case shall the total project period exceed any applicable statutory limit or expiring appropriation limitation. The terms and conditions of award include information about no-cost extensions of the award and when ADO’s prior approval is necessary.

f. Changes in Approved Budget: Unless stated otherwise in the terms and conditions of award, changes in an approved budget must be requested by the awardee and approved in writing by the ADO prior to instituting such changes, if the revision will involve transfers or expenditures of

amounts requiring prior approval as set forth in the applicable Federal cost principles, Departmental regulations, or award.

C. Confidential Aspects of Applications and Awards

When an application results in an award, it becomes a part of the record of NIFA transactions, available to the public upon specific request. Information that the Secretary determines to be of a confidential, privileged, or proprietary nature will be held in confidence to the extent permitted by law. Therefore, any information that the applicant wishes to have considered as confidential, privileged, or proprietary should be clearly marked within the application. The original copy of an application that does not result in an award will be retained by the Agency for a period of three years. Other copies will be destroyed. Such an application will be released only with the consent of the applicant or to the extent required by law. An application may be withdrawn at any time prior to the final action thereon.

D. Regulatory Information

For the reasons set forth in the final Rule related Notice to 7 CFR part 3015, subpart V (48 FR 29114, June 24, 1983), this program is excluded from the scope of the Executive Order 12372 which requires intergovernmental consultation with State and local officials. Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collection of information requirements contained in this Notice have been approved under OMB Document No. 0524-0039.

E. Definitions

Please refer to 7 CFR 3415, Biotechnology Risk Assessment Research Grants Program, and 7 CFR 3430, Competitive and Noncompetitive Non-formula Grant Programs--General Grant Administrative Provisions, for the applicable definitions for this NIFA grant program. If a conflict exists between these regulations, the language in 7 CFR 3415 is overriding.